

REMARKS

Status of the Claims

Claims 4, 6, and 10-14 are pending in the present application. Claims 4, 6, and 10-14 have been amended as described elsewhere herein. No new matter has been added by way of amendment.

The Restriction Requirement

In the Office Action, the Examiner has maintained the requirement for the election of a species consisting of a single point of interaction between the ErbB4 kinase domain in liganded form and the compounds to be evaluated. Applicants again request reconsideration of this requirement. According to *MPEP* § 1893.03(d), "[a] group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature." In the present case, there is a technical relationship between species i-xxxi as listed in the Supplemental Restriction Requirement because all are potential sites of interaction between the ErbB4 kinase domain having the structural coordinates shown in Table 2 and a compound that is a potential inhibitor. Because all points of interaction listed in the claims are based on the structure of the ErbB4 kinase domain in liganded form having the recited structural coordinates, these points of interaction share a technical relationship. Accordingly, the species identified in the Supplemental Restriction Requirement are linked to form a general inventive concept and should be examined together.

Information Disclosure Statement

The Examiner states that Reference No. 2 (Cox *et al.*) listed on Form PTO-1449 submitted on June 6, 2007 was not considered because the document was not in the file. Applicants' representative apologizes for the inconvenience caused by the failure to provide a copy of this reference. A copy of Cox *et al.* is attached herewith, along with the appropriate statement and fee and a new Form PTO-1449. Applicants request that the Examiner consider this reference and return a fully initialed copy of the Form PTO-1449 with the next communication.

Objections to the Declaration

The Examiner has correctly noted that the Declaration executed by the inventors contains a typographical error in the filing date for PCT/US04/01291. The inventors have executed a new Declaration, and copies of this new document are included herewith. Applicants' representative apologizes for any inconvenience caused by this error.

The Objections to Specification

The Office Action states that the title of the invention is not sufficiently descriptive. Applicants have amended the title to reflect the invention currently claimed, thereby obviating the objection.

The Office Action states that the specification does not comply with the requirements for a sequence listing. Applicants submit herewith a new sequence listing which lists the amino acids listed in Table 2, as well as the two peptide sequences listed in the Experimental section of the specification. The specification has been amended to provide the new sequence identifiers. Applicants request that the this new sequence listing be entered into the specification.

The Rejection Under 35 U.S.C. § 112, Second Paragraph, Should be Withdrawn

Claims 4, 6, and 10 have been rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the term "represents" is indefinite. Applicants believe that the meaning of this term would be clear to those of skill in the art in the context of this claim. Nevertheless, in order to expedite prosecution, this term has been deleted from claims 4, 6, and 10-14.

Claim 4 has been rejected under 35 U.S.C. § 112, second paragraph, on the grounds that the phrase "evaluating compounds" is unclear. Applicants respectfully traverse the rejection. The specification provides extensive guidance regarding the evaluation of compounds. See, for example, the first paragraph of page 33 of the specification *et seq.* Accordingly, one of ordinary skill in the art, reading the claims in light of the supporting specification, would be able to ascertain the metes and bounds of these claims.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, second paragraph, have been obviated or overcome. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

The Rejection Under 35 U.S.C. § 112, First Paragraph, Should be Withdrawn

Claims 4, 6, and 10 have been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that these claims lack a sufficient written description. The Examiner states that the term "represents" in these claims is unclear, and that the claims have therefore been construed to encompass the use of ErbB4 kinase domains that do not have the structural coordinates listed in Table 2. The Examiner states that the present application does not contain sufficient written description of ErbB4 kinase domains that do not have the structural coordinates listed in Table 2. Claims 4, 6, and 10 have been amended to delete the term "represents" as described above in the response to the rejection under 35 U.S.C. § 112, second paragraph, thereby obviating the rejection.

Claims 4, 6, and 10 have also been rejected under 35 U.S.C. § 112, first paragraph, on the grounds that these claims are not supported by sufficient enablement. The Examiner states that the term "represents" in these claims is unclear, and that the claims have therefore been construed to encompass the use of ErbB4 kinase domains that do not have the structural coordinates listed in Table 2. The Examiner states that the present application does not contain sufficient enablement for use of ErbB4 kinase domains that do not have the structural coordinates listed in Table 2. Claims 4, 6, and 10 have been amended to delete the term "represents" as described above in the response to the rejection under 35 U.S.C. § 112, second paragraph, thereby obviating the rejection.

In view of the above arguments and amendments, all grounds for rejection under 35 U.S.C. § 112, first paragraph have been obviated. Accordingly, reconsideration and withdrawal of the rejections are respectfully requested.

The Rejection under 35 U.S.C. § 103 Should be Withdrawn

Claims 4, 6, and 10 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Groenen *et al.* (*Biochem.* 36:3826-3836, 1997) in view of Cohen *et al.* (*J. Med. Chem.* 33:883-894, 1990); Traxler *et al.* (*Pharmacol. Ther.* 82:195-206, 1999); Plowman *et al.* (*PNAS* 90:1746-1750, 1993); and U.S. Patent No. 5,804,396 (the '396 patent). The rejection is respectfully traversed for the reasons described below.

The rejection hinges on the construction of the scope of claims 4, 6, and 10. As noted above, the Examiner has stated that the term "represents" in these claims is unclear, and that the claims have therefore been construed to encompass the use of ErbB4 kinase domains that do not have the structural coordinates listed in Table 2. The Examiner argues that Groenen teaches an EGFR kinase domain homology model, and that it would be obvious to use such a model in the identification of inhibitors in view of Cohen *et al.*, Traxler *et al.*, and Plowman *et al.* As noted previously claims 4, 6, and 10 have been amended to delete the term "represents," thereby obviating this aspect of the rejection.

The Examiner also argues that the atomic coordinates recited in claims 4, 6, and 10 constitute nonfunctional descriptive matter, and that these atomic coordinates should therefore not be considered in construing the scope of the claims. The Examiner argues that when the limitation of the recited atomic coordinates is not considered, claims 4, 6, and 10 are obvious in view of the cited references. According to the Office Action, the structural coordinates of Table 2 are non-functional because they do not have a functional relationship with the computer on which they are stored. The Examiner states that, "[d]ata, which are fed into a known algorithm whose purpose is to compare or modify those data uses a series of processing steps, do not impose a change in the processing steps and are thus nonfunctional descriptive material." (May 27, 2008 Action, page 19) Thus, according to the Office Action, there is a *per se* rule that data stored in a computer is considered to be non-functional if the data does not affect how the computer performs its function.

However, the relevant case law does not support a finding that the atomic coordinates recited in claims 4, 6, and 10 are non-functional descriptive matter. In *In re Gulack*, 703 F.2d 1381 (Fed. Cir. 1983), the Federal Circuit stated:

A functional relationship of the precise type found by the CCPA in *Miller*—to size or to type of substrate, or conveying information about substrate—is not required. What is required is the existence of *differences* between the appealed claims and the prior art sufficient to establish patentability . . . the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.

Id. at 1386. In the present case, claims 4, 6, and 10 are directed to methods of using of using structural information about a novel ErbB4 liganded kinase domain in the design of ErbB4 inhibitors that fit spatially into this novel kinase domain. The atomic coordinates recited in the

claim 4 are integral to the step of modeling a ligand that fits spatially into the liganded kinase domain pocket. If a different set of atomic coordinates were used in the claimed method, the result of the method would differ from the result achieved in the method recited in claim 4. Thus the atomic coordinates recited in claim 4, 6, and 10 functionally affect the process of modeling an inhibitor to fit within the liganded kinase domain pocket. Accordingly, the atomic coordinates are functionally related to the claimed method and this limitation should be considered when construing the scope of these claims. The Examiner has not produced any evidence that the liganded kinase domain described by the recited atomic coordinates would be obvious in view of the prior art references. Accordingly, claims 4, 6, and 10 recite differences over the prior art that are sufficient to establish patentability, thereby meeting the standard for non-obviousness set forth in *Gulack*.

In summary, over Groenen *et al.*, Cohen *et al.*, Traxler *et al.*, Plowman *et al.*, and the '396 patent, either alone or in combination, do not teach or suggest all the limitations of claims 4, 6, and 10 when all the limitations of these claims are properly considered. Therefore, all grounds for rejection under 35 U.S.C. § 103 have been overcome. Reconsideration and withdrawal of the rejection are therefore respectfully requested.

CONCLUSION

It is believed that the current application is now in condition for allowance. Early notice to this effect is solicited. If, in the opinion of the Examiner, an interview would expedite prosecution, the Examiner is invited to call the undersigned.

Applicants believe that no fees are due in connection with the filing of this paper other than those specifically authorized herein. However, should any other fees be deemed necessary to effect the timely filing of this paper, the Commissioner is hereby authorized to charge such fees to Deposit Account No. 07-1392.

Respectfully submitted,

Kathryn L. Coulter
Kathryn L. Coulter
Patent Attorney
Registration No. 45,889

Date: 9/29/2008
Customer No. 23347
GlaxoSmithKline
Corporate Intellectual Property Department
Five Moore Drive, P.O. Box 13398
Research Triangle Park, NC 27709-3398
Telephone: (919) 483-1467
Facsimile: (919) 483-7988